

SUPREME COURT OF THE STATE OF NEW YORK  
COUNTY OF SUFFOLK: PART 48

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IN RE: OPIOID LITIGATION

INDEX NO.: 400000/2017

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July 12, 2021  
Central Islip, New York

MINUTES OF TRIAL

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                                      Supreme Court Justice

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THE CLERK: Supreme Court is now in session. The Honorable Jerry Garguilo presiding.

Good morning, your Honor.

THE COURT: Good morning everybody. Good morning. Please be seated.

THE CLERK: This is continuing trial In Re: Opioid Litigation. Jury is not present.

So yesterday I'm looking at my email 5 p.m. goes by, nothing; 6 p.m. goes by, nothing; 7 p.m., I'm doing good. 8 p.m. I'm watching Shark Week, that was almost appro po. Nine o'clock, now I'm giving one of these, right. Then 9:20, boom, the phone goes off. And you folks, some of you continue to submit after the midnight hour.

I need some help. I spent sometime this weekend, for instance, on the Day, D-A-Y, transcripts, and we also spent sometime on the one, actually, I think it's Pyfer.

Oh, Brennan, excuse me. I did Day myself, of course, and I asked for the assistance of my law secretary, Miss Galteri, in connection with Brennan.

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2 I'm aware of the issue that was brought  
3 up by Mr. Oleske on Friday. I'm trying to  
4 look for a method that makes it manageable  
5 for the Court to inform you as to what the  
6 Court's rulings are on the contested portions  
7 of each deposition.

8 And, Mr. Oleske, as I understand it, the  
9 only assistance, as far as your research in  
10 the case, the only assistance, and if I'm  
11 wrong you'll tell me, that the Court can  
12 reach out for is with a "judicial employee."

13 MR. OLESKE: Yes, your Honor. Including  
14 the law department. So I think --

15 THE COURT: According to research, I can  
16 access the law department?

17 MR. OLESKE: The direction from the case  
18 law is, in fact, that's what a reverse  
19 saying, the Court should have relied on the  
20 law department.

21 THE COURT: It should?

22 MR. OLESKE: Yes.

23 THE COURT: So, in other words, if I  
24 engage the assistance of the law department,  
25 we're okay.

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2 MR. OLESKE: That's what the case law  
3 suggests, your Honor, yes.

4 THE COURT: All of you feel the same  
5 way? I don't see anybody saying no.

6 MR. PRESNAL: Well, Judge --

7 THE COURT: Understand something,  
8 nothing leaves my desk. Nothing leaves my  
9 desk without an intensely careful review  
10 so...

11 MR. PRESNAL: Judge, we did a little bit  
12 of research over the weekend, and I do think  
13 that you could appoint referees to hear and  
14 report on these issues, which is what I think  
15 you have in mind. In other words, not to  
16 make direct rulings, but to make  
17 recommendations to you.

18 We're still discussing that issue with  
19 the Defendants, and we're not all on the same  
20 page, although I do think that we, in general  
21 terms, see it the same way.

22 THE COURT: If by the end of the day you  
23 can tell me if there's any consensus, of  
24 course, I'll hear it.

25 MR. PRESNAL: There may be some

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procedural requirements of doing it via the  
hear and report method that have to be done,  
but that seems to be what the options --

THE COURT: You mention job title of  
people in the law department, the court  
attorney referee, that's their actual job  
title.

Okay, next step. I spent some time  
reviewing the past short form orders of this  
Court in connection with many of the issues  
that I anticipate hearing this morning.

Oh, by the way, does anybody know what  
July 17th is -- excuse me, June 17th is? I  
think it's the anniversary, I think it's the  
date that I got the assignment from the  
coordinating panel. I'll serve cupcakes,  
something.

Now, go back to June 18th, 2018, motion  
sequence 001 through 0019, which was  
originally -- which was -- it was an  
all-encompassing motion to dismiss. The part  
and parcel of it was Endo's petition to  
dismiss for referencing the AOD. As you  
know, that motion was denied.



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At page 16 in this Court's short form order I noted the following -- and, by the way, I raise this because it was also raised in the motions in limine that were submitted prior to the commencement of trial.

At page -- again, at page 16, Endo's argument pursuant to CPLR 3211(a)(5) that the Plaintiffs' claims against it are barred by an assurance of discontinuance executed on March 16th -- excuse me -- March 2016 concerning its marketing Opana ER, its branded version of the semi-synthetic opioid analgesic Oxymorphone, is rejected.

On page 17 the Court goes on to note: In addition, the assurance states that nothing contained herein shall be construed to deprive any member or other person or entity of any private right under law or equity, and that it does not limit in any way the Attorney General's power to take actions against Endo for either noncompliance with its terms or noncompliance with any applicable order as to "with respect to any matters that are not part of the covered

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conduct." We do know, of course, the subject matter of the AOD was Opana, and there was again a cutoff date of 2016.

The Court further notes on the page 18: Moreover, the March -- moreover, the March 2016 assurance of discontinuance does not immunize Endo from civil actions for subsequent fraudulent activities within New York or bar the counties from bringing law or equity claims against it for practices within their respective jurisdictions.

Now, keep in mind, that motion way back when, that's sequence 001, did not involve the State. It was -- at that point the only Plaintiffs participating were all the Counties.

At motion sequence 064, the Court made additional findings, again, as concerns the AOD issues, at page 3: In addition, the assurance of discontinuance states that, again, nothing contained herein shall be construed to deprive any member or person or entity of any private right under law or equity. Again, that was, of course, noted in

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the early decision. And it does not limit in any way the Attorney General's powers to take actions against the moving Defendants for either noncompliance with its terms or noncompliance with any of the applicable law.

Then it notes: With respect to any matters that are not part of the covered conduct, significantly, the moving Defendants neither admitted or denied the Attorney General's various findings of unlawful practices, statements or omissions under the General Business Law 349 and 350 regarding the marketing of Opana.

On the same page it notes: The March 2016 assurance of discontinuance does not bar the various claims asserted against the moving Defendants by the Attorney General in the instant action. While the assurance of discontinuance is an enforceable contract between the Attorney General and the moving Defendants, the purpose of such agreement was to resolve, without formal litigation, the claims that the moving Defendants engaged in deceptive consumer practices in violation of

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General Business Law 349 and 350 in the  
marketing of Opana.

Then at motion sequence 163, once again,  
the AOD issue comes up, including today it's  
the sixth time we've heard about it.

The Court notes at page 2: The  
Defendants argue that they are entitled to an  
order barring the State of New York from  
predicating this public nuisance claims on  
evidence related to their marketing of Opana  
ER during the period prior to 2016 and on  
evidence related to their unbranded marketing  
of prescription opioids in general.

Again, I think there's a Stipulation in  
the motions in limine that the State will not  
go into Opana marketing prior to the  
effective date of the AOD.

Then this decision at page 2 goes on to  
note the following: In any event, the  
Defendants failed to demonstrate a prima  
facie case that the March 2016 agreement with  
the Attorney General extended to their  
marketing and supply of prescription opioids,  
other than Opana. Fundamental principle of

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contract interpretation is that an agreement should be construed in accordance with parties' intent. The best evidence of what the parties -- the best evidence of what the parties' Agreement intends what they say in their writing. In a written agreement that is complete, clear and unambiguous on its face must be enforced according to its planned meaning.

Then at page 3: The Defendants failed to make a prima facie case that the term covered conduct in the assurance of discontinuance must be interpreted as including the promotion and marketing of Opana ER and other prescription opioids performed by third parties.

Instead, the language shows that the Attorney General's inquiry was directed at the Defendants' own statements, misstatements and omissions about Opana ER, particularly those made in printed materials posted on their public website and conveyed to their sales representatives to health providers, and that it concluded their marketing

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practice, statements and omissions regarding that prior violated General Business Law 349 and 350.

Then again at motion sequence 236, again, the AOD issue came up. In connection with a petition seeking severance, the Court noted any potential prejudice to Endo flowing from the AOD is better dealt with a careful -- with careful instructions to the jury rather than trying the case three times, which was suggested in the petition, so three trials involving Endo.

There was a presumption that jurors will obey a judge's limiting instructions, see Robert A. Baker and Vincent Alexander evidence in New York State and federal courts Section 1-19, second edition.

Then you go through the rulings of this Court in connection with the form motions in limine, go to page 7, one-third down the page: Defendant Endo's motion in limine regarding its assurance of discontinuance with the State, the ruling, the Court will abide by its short form orders as concerns

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2 the AOD.

3 That's a history of the litigation  
4 involving the AOD. It seems to the Court  
5 that, and I believe it's been stipulated,  
6 that as the AOD or anything in it reflects on  
7 the marketing of Opana prior to the -- up to  
8 the date of the AOD is out of bounds, but any  
9 other products are, in fact, not barred by  
10 the language of the assurance of  
11 discontinuance.

12 MR. REISMAN: Your Honor, if I may?

13 THE COURT: Is it Reisman or Reisman  
14 (pronouncing)?

15 MR. REISMAN: If I may just interject  
16 for a moment.

17 THE COURT: I beg your pardon?

18 MR. REISMAN: If I may just interject  
19 for a moment. Michael Reisman from the  
20 Attorney General's office for the State of  
21 New York.

22 In fact, there is no -- your Honor  
23 referred just now to a Stipulation. I am not  
24 aware of any such Stipulation. There is a --  
25 the AOD is a document, of course, that the

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Court has considered, but with respect to the issues at hand, the State late last night, apologies for the lateness, about 11:30, filed the letter with the Court attempting to delineate these issues, and the issue is that the AOD, as your Honor has observed, and as Endo's counsel has observed, relates to marketing of Opana ER. That evidence, as your Honor knows, may come in still if it addresses other issues, such as Endo's use of front groups and KOLs, third passage --

THE COURT: The third part involving as per this Court's prior short form orders is allowable.

MR. REISMAN: Okay.

THE COURT: If that's what you're saying. It specifically says that in the Court's prior determinations.

MR. REISMAN: Yes, your Honor.

In our letter last night we explained that because this is a public nuisance action, evidence concerning Endo's knowledge of abuse and diversion, including its knowledge gained through marketing and



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research and so on regarding Opana ER, is within bounds. It is within bounds because, as your Honor saw in the letter, after March 1st of 2016, the FDA asked Endo, in a very extraordinary situation, to withdraw, reformulate Opana ER from the market due to the risks of abuse. And then ultimately Endo did that, and Opana ER, the reformulated version, was pulled from the market and, ultimately, the FDA withdrew its approval.

So our position is that the events post March 1st 2016 call into question: What did Endo know and when did they know it about the abuse and diversion of Opana ER?

And just one final point I would make, your Honor, and apologies if I was not clear about this on Friday, the AOD specifically concerns Opana ER. It does not concern Opana immediate release or Opana IR.

The Oxymorphone document that your Honor considered on Friday refers generally to Oxymorphone. It does not refer specifically to Opana ER or Opana IR. So that is another key distinction as we made in the letter that

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2 was filed last night.

3 MR. SOLOW: Andrew Solow for the Endo  
4 Defendants.

5 THE COURT: Good morning, Mr. Solow.

6 MR. SOLOW: Your Honor, we don't  
7 disagree with your Honor's recitation of the  
8 history of the AOD motions, and I acknowledge  
9 there have been several of them.

10 If I could, your Honor, to simplify  
11 things moving forward. Your Honor's rulings  
12 were as stated. If we could just have a  
13 continuing objection on our position, as your  
14 Honor knows, we have now up in front of the  
15 Appellate Division on issues that your Honor  
16 has ruled are outside the AOD, that could  
17 certainly streamline things. That's my first  
18 request, your Honor.

19 THE COURT: The answer is yes,  
20 continuing objection -- continuing exception  
21 noted.

22 MR. SOLOW: Thank you, your Honor.

23 So turning then, your Honor, to the  
24 issue at hand is what appears to be a  
25 disagreement about the scope of marketing

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that is covered conduct.

As your Honor knows, you asked on Friday for us to provide you a history in a submission to Miss Liccardi. I sent that email last night, I believe before the Shark Week viewing.

Your Honor, I call your specific attention to the covered conduct paragraphs of the AOD, paragraphs 11 through 35.

So while your Honor's short form orders refer, respectfully, in the shorthand to marketing, if you review those paragraphs of the covered conduct, there are quite a bit of subsections within there. And I'll just read those titles for the record, your Honor. There is covered within "Covered Conduct," the crush-resistance of reformulated Opana ER. The addictiveness of Opana. Certain statements distinguishing Opana ER from OxyContin. Certain statements that suggest you can achieve higher functions from Opana ER. Statements and omissions related to Opana ER studies. Detail of problem New York healthcare providers by certain Endo sales

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representatives in connection with the promotion of Opana ER. Marketing statements directed to healthcare providers and patients.

So, your Honor, our position, within the scope of your Honor's short form orders, is that there is quite an extensive amount of "covered conduct" covered by the AOD. And all we are asking for, your Honor, consistent with what your Honor ruled on Friday, is those items are out of bounds for the Attorney General.

I did read Mr. Reisman's letter last night after at 10 to 12 and, your Honor, that's the issue. It appears to us there is an attempt at overreaching. Again, it harkens back to this concept of Courtwright -- Dr. Courtwright. That even though they seem to on one side be saying, yes, we acknowledge the marketing prior to March 2016 is out, they then say, but we're allowed to actually put that evidence in to support other claims about conduct that happened after 2017.

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Your Honor, our position is that is a clear violation and out of bounds.

THE COURT: How about I'm willing to read to the jury that portion of the AOD?

MR. SOLOW: Well, your Honor, if I may. That's why I referred your Honor to the motion in limine, not to reargue the motion, but your Honor asked us to refresh your recollection.

THE COURT: You did.

MR. SOLOW: Right. And that's the issue, your Honor. It is a Settlement Agreement. As set forth in the case law in our motion in limine, the jury is not entitled to rely upon that.

I understand your Honor is now taking the position that the way to work around this are limiting instructions, that's the problem. You now have -- if you want to submit to the jury the issue of what covered conduct is, right, your Honor noted in the short form orders we neither admit nor deny any of that.

So on one hand we're now going to have

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the jury deciding factual issues about why -- what the State is barred from proceeding under this cause of action. On the other hand I've got the same jury who's deciding the case against the Counties who are not allowed to know about the Settlement Agreement, because it's a Settlement Agreement, there is significant case law on that. There are not admissions, contrary to arguments your Honor has heard, it can't go to notice. So that's the problem, your Honor.

And I understand and respect the fact that your Honor has ruled on that, and we've taken it up on appeal, but that's the very issue, your Honor.

At a certain point, now that you have granted us a continuing objection around what is -- what your Honor has held is not marketing, for example, third-party marketing, the issue, your Honor, of now debating and letting the State put in as an issue of fact whether, for example, the Opana ER pre-approval training manual, which there

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1 is deposition testimony establishing without  
2 a doubt that it is the Opana ER training  
3 manual, your Honor instructed the jury Friday  
4 they're not allowed to consider that for the  
5 State, but now we're going to have the State  
6 use that document just so the jury can  
7 determine that, in fact, it is covered under  
8 the AOD.  
9

10 In the meantime, the jury, as the  
11 Counties' jury, is now hearing the very  
12 Settlement Agreement they're not entitled to  
13 hear because there are no admissions. It  
14 does not go to notice. So, admittedly, your  
15 Honor, that's the conundrum we have.

16 So I don't believe submitting -- reading  
17 paragraphs 11 through 35, which we neither  
18 admit nor deny to the jury, just to allow Mr.  
19 Reisman to use a document which, candidly, we  
20 think, as a matter of law, your Honor can  
21 determine is clearly, under your short form  
22 orders, covered as a covered conduct. That's  
23 the issue, your Honor.

24 THE COURT: Thank you.

25 Mr. Reisman, very briefly.

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MR. REISMAN: Yes, sir, understood.

So to cut to the chase here, so there is a type of evidence regarding Endo, Endo's statements made during marketing to healthcare providers regarding the alleged crush-resistant properties of reformulated Opana ER. The State has no intention of introducing that type of evidence in this trial.

THE COURT: That's what I was referring to. Yeah, keep going.

MR. REISMAN: Yes. Yes. And I think we're agreed on that.

However, there is evidence concerning Endo's knowledge of abuse and diversion at the company level, at the marketing executive level, their call plan strategies, the extent of their detailing in New York, the extent of their payments to healthcare providers in New York, generally, as reflected in things like open database, all those sorts of, types of evidence are relevant to the question of what Endo knew about abuse and diversion of opioids generally and regarding Opana ER



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specifically because, as we know, it was withdrawn from the market because of abuse, and that happened after March 1st 2016 and that brings into play, it brings within bounds, all of the evidence regarding what Endo knew.

THE COURT: Okay. Bring the witness in, please.

Make your objections in realtime.

MR. SOLOW: Thank you, your Honor.

THE COURT: I'm reserving all your objections and your exceptions. Make them in realtime also. The witness, please.

Oh, by the way, somebody noticed there may be some Jewish holidays coming up real soon. There was actually an article in the Long Island paper yesterday about three that are coming up real soon. So we'll make some inquiries with the administration here as to the availability of the facilities on those days.

Good morning, Doctor.

THE WITNESS: Good morning.

THE CLERK: Good morning, Doctor. I

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2 remind you you're still under oath. You may  
3 be seated.

4 THE COURT: Bring the jury in, please.  
5 Thank you.

6 THE CLERK: All jurors are present and  
7 properly seated, your Honor.

8 THE COURT: Please be seated everybody.  
9 Ms. Conroy.

10 MS. CONROY: Thank you, your Honor.  
11 Good morning. Good morning, your Honor.  
12 Good morning, Dr. Lembke.

13 THE WITNESS: Good morning.

14 MS. CONROY: Welcome back.

15 THE WITNESS: Thank you.

16 CONTINUED DIRECT EXAMINATION OF DR. LEMBKE BY  
17 MS. CONROY:

18 Q. Just to sort of recap for everyone, last  
19 week we talked about addiction, correct?

20 A Yes.

21 Q. And withdrawal, tolerance, dependence,  
22 we talked about those concepts?

23 A Yes, we did.

24 Q. Okay. And you also spoke about dose and  
25 duration of the medication, how long someone took an

1 Continued Direct/Dr. Lembke 27

2 opioid and how high the dose might have been.

3 A Yes.

4 Q. And you explained chronic pain versus  
5 acute pain versus cancer pain.

6 A Yes.

7 Q. Okay. And you also talked about the  
8 methods that promotional messages could reach  
9 doctors. Could you just give me -- just remind the  
10 jury specifically what those were.

11 A Promotional messages reach doctors  
12 through what's called drug reps who are employed by  
13 the pharmaceutical industry to go out to doctors'  
14 offices and hospitals to market their products.

15 MR. PYSER: Objection, your Honor.

16 Just a clarification of the term "the  
17 pharmaceutical industry."

18 THE COURT: Yes. Ms. Conroy, we  
19 discussed that the term --

20 MS. CONROY: Yes.

21 Q. Do you recall that?

22 THE COURT: Dr. Lembke --

23 A Yes. So they're hired by certain opioid  
24 manufacturers to go out to the doctors' offices and  
25 hospitals to market certain opioid products, but

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2 promotional messages are also conveyed through  
3 things like continuing medical education, which  
4 doctors are required to attend in order to maintain  
5 licensure.

6 The point of continuing medical  
7 education is to keep them up-to-date on science.  
8 Promotional messages are also conveyed through key  
9 opinion leaders who are leaders in their field,  
10 often from prestigious institutions who are in many  
11 cases receiving payment from certain opioid  
12 manufacturers to go and give these talks and promote  
13 what certain opioid manufacturers call their key  
14 promotional messages.

15 Opioids are also promoted through  
16 journal articles that are published in peer-review  
17 literature. These studies are sometimes funded by  
18 the opioid manufacturers and/or the authors are  
19 employed by certain opioid manufacturers or are paid  
20 consultants of certain manufacturers.

21 Certain opioid manufacturers also  
22 promote their messages by ingratiating themselves  
23 and lobbying certain regulatory bodies, so the State  
24 regulatory bodies or things like Joint Commission,  
25 which I talked about, which is an organization that

1 Continued Direct/Dr. Lembke 29

2 accredits hospitals without which those hospitals  
3 would not be able to receive payments from insurers  
4 like Medicare.

5 Certain opioid manufacturers have also  
6 created relationships with the Federation of State  
7 Medical Boards, and you'll remember the Federation  
8 of State Medical Boards is the organization that  
9 polices doctors to make sure that they are not  
10 engaged in unsafe and dangerous practices; that they  
11 are, as the hippocratic oath would say, first do no  
12 harm in their treatment of patients.

13 Q. Thank you.

14 The next topic I would like to get into  
15 with you is: What is the rate of addiction to  
16 prescription opioids when they are used to treat  
17 chronic pain patients? Do you know that rate?

18 A Yeah. So I've looked extensively at the  
19 scientific literature on this topic, which is to say  
20 the topic of how many people who are prescribed  
21 opioids by their doctor for a chronic pain condition  
22 have an opioid addiction, and the most reliable  
23 evidence shows that about 8 to 12 percent of  
24 patients getting an opioid from a doctor for a  
25 chronic pain addiction have an opioid addiction.

1 Continued Direct/Dr. Lembke 30

2 Q. That's 8 to 12 percent?

3 A Yes.

4 Q. What do you rely on for this figure?

5 A I rely primarily on a meta-analysis by  
6 Vowles. Meta-analysis is the study that combines a  
7 bunch of different studies into one and analyzes  
8 that data to come up with a number that represents  
9 all of those studies, and the Vowles is the  
10 definitive work on this question because it includes  
11 studies that specifically set out to find out the  
12 rates of misuse and addiction among chronic pain  
13 patients getting opioids from their doctor.

14 In comparison to other studies that have  
15 claimed to explore this question, which don't  
16 actually ask patients about misuse and addiction,  
17 but expect patients to volunteer that information  
18 and base their results on whether or not the patient  
19 brought it up themselves, and that's highly  
20 problematic, because misuse, opioid misuse, and  
21 opioid addiction are highly shameful behaviors.  
22 Patients would not naturally volunteer to their  
23 doctor that they're misusing the opioids their  
24 doctor is giving them.

25 So it's really essential when trying to

1 Continued Direct/Dr. Lembke 31  
2 figure out the rates of addiction in this population  
3 that we do things like ask the patient about it or  
4 give them questionnaires that might explore that or  
5 test their urine for the presence of that drug or  
6 another drug. And Vowles has exactly done that, the  
7 study that I rely on.

8 It's taken new world patients from  
9 primary care clinics, from pain clinics, and it's  
10 included only those studies that actually sought to  
11 illicit the specific information about whether those  
12 patients were misusing or addicted to opioids.

13 Q. And so that study determined 8 to 12  
14 percent of the patients would become addicted,  
15 correct?

16 A That study shows that among chronic pain  
17 patients taking an opioid, about 8 to 12 percent of  
18 them are addicted to opioids.

19 Q. And what does that mean with respect to  
20 the risk of addiction, how does that fall in line, 8  
21 to 12 percent; what does that mean?

22 A So in medicine if you're trying to  
23 communicate to patients or providers whether or not  
24 a risk is common, uncommon, very common, a very good  
25 point of reliance is a scale from World Health

1 Continued Direct/Dr. Lembke 32

2 Organization. And the World Health Organization has  
3 said that if the risk of an adverse event from  
4 taking a drug is somewhere between 1 percent and 10  
5 percent, then that's a common risk and they use the  
6 language of common. If the risk is greater than 10  
7 percent, that is considered very common.

8 So according to the Vowles  
9 meta-analysis, with the risk of 8 to 12 percent,  
10 that means that the likelihood of being addicted in  
11 a population of chronic pain patients getting  
12 opioids is common to very common.

13 I would also add that this definition of  
14 common to very common is the same definition that  
15 can be found in some opioid manufacturer labels.

16 So, for example, a label for Opana ER,  
17 which is an Endo product, says in the label that a  
18 risk factor is common if it is between 1 and 10  
19 percent of the population manifesting that problem  
20 as a result of taking the drug.

21 Q. And so the risk of addiction to  
22 prescription opioids when taken by a chronic pain  
23 patient is a far cry from rare, correct?

24 A That is correct.

25 Q. Now, I would like to move on to talk



1 Continued Direct/Dr. Lembke 33

2 with you about some specific promotional messages,  
3 and I'd like you to refer to what was marked as  
4 Exhibit P-27812. It is pretty big and it has -- it  
5 has an email on the front, but what I'm going to be  
6 asking you about is the document that has Kadian on  
7 it with a ribbon. 27812.

8 A Yes, I have that.

9 Q. Doctor, what is the drug Kadian?

10 A Kadian is a long-acting form of  
11 morphine.

12 Q. And if you could turn to, I think it  
13 might be easiest if I give you the actual page of  
14 the document and then I'll give you the Bates No.  
15 So page 28 of the document and the Bates No. is --  
16 I'll put it up here -- Allergan MDL 01610549; do you  
17 have that page?

18 A Yes, I do.

19 Q. And we spoke a little bit about this on  
20 Friday. Do you see the term it says: Despite the  
21 improvements in pain management that have occurred  
22 over the past decade several barriers to effective  
23 pain control remain, and do you see the third bullet  
24 point, opioid phobia?

25 A Yes, I see that.

1 Continued Direct/Dr. Lembke

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2 Q. Okay. And what is opioid phobia?

3 A Opioid phobia, in the way that it is  
4 used here, refers to an irrational fear on the part  
5 of the prescriber that their, that their patient  
6 will get addicted to opioids through their  
7 prescription.

8 Q. And now I'd like you to turn to page 31  
9 of the document, and it's Allergan MDL 01610552.  
10 And if you could take a look at the very bottom it  
11 says: Although some progress has been made in  
12 providing good pain control to every patient, many  
13 factors still interfere with pain management. These  
14 include inadequate education of healthcare  
15 providers, fear of regulatory action by clinicians  
16 and inappropriate fear of addiction.

17 Do you see that?

18 A Yes, I do.

19 Q. Is it inappropriate for a clinician or a  
20 physician prescribing an opioid to a chronic pain  
21 patient to fear addiction?

22 A No, it is not.

23 Q. And why is that?

24 A Because, as I just said, the risk of  
25 becoming addicted through a doctor's prescription

1 Continued Direct/Dr. Lembke 35

2 for treatment of chronic pain is actually common or  
3 very common. Anybody can get addicted.

4 Q. And is it actually inappropriate in a  
5 learning manual for sales representatives, who are  
6 going to promote Kadian, to suggest that a fear of  
7 addiction is inappropriate?

8 A Yes. I believe that these kinds of  
9 statements are false and misleading and shouldn't  
10 have been included in training manuals.

11 Q. Next, I'd like you to turn to page 76 of  
12 the manual, and it is Allergan MDL 01610597, on page  
13 76 of the manual. And do you see what I have  
14 highlighted here: Substance abuse will be seen in a  
15 few patients in every -- what does CBP stand for?

16 A Chronic benign pain.

17 Q. And what is chronic benign pain?

18 A Non-cancer pain.

19 Q. And it goes on to say: Perhaps largely  
20 because patients attempting to obtain opioids will  
21 eventually end up at a pain management practice.  
22 However, despite the continued unscientific beliefs  
23 of some clinicians, there is no evidence that simply  
24 taking opioids for a period of time will cause  
25 substance abuse or addiction.

1 Continued Direct/Dr. Lembke

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2 Do you see that?

3 A Yes, I do.

4 Q. Is that true?

5 A No, it is not.

6 Q. Is it false?

7 A Yes, it's false.

8 Q. Now, if you go further down on the page,  
9 it says at the very last line: Educating clinicians  
10 about these guidelines will help to ease their fears  
11 of prescribing for patients with chronic benign  
12 pain, and it's under a section entitled: Guidelines  
13 for Opioid Use in Chronic Benign Pain.

14 Do you see that?

15 A Yes, I do.

16 Q. Can you explain to the jury what is  
17 meant by "guidelines."

18 A Guidelines, when that word is used, it  
19 has a strong influence on physicians, especially if  
20 it comes from an esteemed organization or was  
21 authored by leaders in the field.

22 Busy clinicians do not have time, the  
23 way that I have had time, to read them in articles  
24 to establish what the science really shows. They  
25 definitively rely on these condensed guidelines to

1 Continued Direct/Dr. Lembke 37

2 summarize the evidence for them so that they know  
3 how best to practice and care for their patients.

4 So guidelines tend to be very  
5 influential. That word alone carries weight in  
6 terms of informing a clinician's decisionmaking  
7 capacity.

8 Q. And let me just take a moment to ask  
9 you, given your expertise, you are an addiction  
10 specialist, correct?

11 A That's correct.

12 Q. Are you in a different position than  
13 other clinicians to evaluate national guidelines?

14 A Well, I think that I'm -- vis-à-vis the  
15 opioid epidemic?

16 Q. Yes, sorry. I'll be specific, yes,  
17 talking -- not with everything. Your specialty is  
18 addiction, correct?

19 A Yes.

20 Q. So are you in a different position than  
21 a clinician who has a different specialty in  
22 evaluating guidelines with respect to opioids?

23 A Yes. My background and knowledge allows  
24 me to really appreciate what is true and what is  
25 false about these guidelines on the treatment of

1 Continued Direct/Dr. Lembke 38

2 pain using opioids.

3 The average physician out there has very  
4 little training in addiction medicine. We get  
5 almost no training in medical school and, in  
6 general, very little in our residency, which is that  
7 apprenticeship period that follows medical school.

8 So the reason that I was able to see  
9 problems with opioid prescribing in my clinical  
10 practice much earlier than the average clinician is  
11 not because I am smarter or anything like that, it's  
12 because I'm an addiction medicine doctor so they  
13 were coming into my clinic, whereas other types of  
14 clinicians oftentimes they don't have -- well, they  
15 don't have the training and education, even under  
16 the best of circumstances, even with training, it's  
17 hard to detect, and then, of course, in modern  
18 medicine today very often there is not the  
19 opportunity of continuity of care to be able to see  
20 what happens to your patient after you prescribe the  
21 opioid.

22 So it's very, very hard for the average  
23 clinician to see that the opioid epidemic was  
24 happening as it was sort of exploding in our  
25 society.

1 Continued Direct/Dr. Lembke 39

2 Q. And if we could now take a look at page  
3 77 of the manual, which is Allergan MDL 01610598, it  
4 talks about three national guidelines that have been  
5 published. Do you see that?

6 A Yes.

7 Q. And one is the American Academy of Pain  
8 Medicine; do you know what that is?

9 A Yes, I do.

10 Q. Okay. And what is that?

11 A That's what's called a professional  
12 medical society, and in this case it's a society of  
13 pain doctors and pain healthcare providers, people  
14 who specialize in the field of pain treatment.

15 Q. And is that the same for the American  
16 Pain Society, the same sort of group?

17 A Yes.

18 Q. And they published a consensus  
19 statement, The Use of Opioids for the Treatment of  
20 Chronic Pain; do you see that?

21 A Yes.

22 Q. And have you reviewed that document?

23 A Yes.

24 Q. And do you have an opinion as to whether  
25 or not it fairly states the risks of addiction to a

1 Continued Direct/Dr. Lembke 40

2 clinician prescribing opioids for a pain patient?

3 A That document states that it actually  
4 recommends opioids in treatment of chronic pain.  
5 So, again, we're not talking about short-term use  
6 for acute pain from which there is good evidence,  
7 we're talking about long-term use greater than three  
8 months of chronic pain for which there is no  
9 reliable evidence, and this document actually  
10 recommends the use of opioids in the treatment of  
11 chronic pain, despite the absence of evidence to  
12 support that.

13 Q. And if you take a look a little further  
14 down, another guideline is the Federation of State  
15 Medical Boards. It's developed model guidelines for  
16 the use of controlled substances for the treatment  
17 of pain. Can you explain for the jury what the  
18 Federation of State Medical Boards is?

19 A So, again, the Federation of State  
20 Medical Boards is like the police of doctors making  
21 sure that doctors are practicing safe medicine and  
22 if they're not, then the Federation of State Medical  
23 Boards can sanction that individual and potentially  
24 even revoke their medical license.

25 Q. And, Doctor, do you know or have you



1 Continued Direct/Dr. Lembke 41

2 researched how the model guidelines came about?

3 A Yes. So in my research, you know, one  
4 of the distressing and shocking discoveries for me  
5 was how many of these regulatory bodies, which I had  
6 just simply assumed were operating based on the best  
7 science, were, in fact, being lobbied by and funded  
8 by certain opioid manufacturers, including  
9 Defendants in this case.

10 And when I struggled to figure out why a  
11 guideline would recommend opioids in the treatment  
12 of chronic pain in the absence of evidence or  
13 profligate the misleading promotional messages that  
14 we've been talking about today and last week, what  
15 came to light in my research was that it's, it's the  
16 funding and a close relationship they had with  
17 certain opioid manufacturers that influenced their  
18 guidelines in absence of the evidence to support  
19 their recommendations.

20 Specifically I -- for example, there's  
21 an organization out of Wisconsin called the Pain and  
22 Policy Study Group, and the Pain and Policy Study  
23 Group was influential in terms of the Federation of  
24 State Medical Boards' guidelines. The Pain and  
25 Policy Study Group received tens of thousands of

1 Continued Direct/Dr. Lembke 42

2 dollars from certain opioid manufacturers and then  
3 aggressively lobbied the Federation of State Medical  
4 Boards to make it easier for doctors to prescribe  
5 opioids at very high doses without getting into  
6 trouble.

7 The Pain and Policy Study Group also  
8 lobbied state legislatures to pass Intractable Pain  
9 Act that basically made it possible for doctors not  
10 to prescribe opioids to patients who asked for them.

11 So, in other words, lobbying by opioid  
12 manufacturers, certain opioid manufacturers and  
13 payments from certain opioid manufacturers to the  
14 Federation of State Medical Boards through front  
15 groups like the Pain and Policy Study Group created  
16 a scenario in which doctors had no choice but to  
17 prescribe more opioids and, essentially, were duped  
18 by these misinformed guidelines and misleading  
19 messages.

20 If I could refer to my report, I'd like  
21 to share a couple of quotes from the leaders of the  
22 Pain and Policy Study Group. Would that be all  
23 right?

24 THE COURT: Doctor, there's an  
25 objection. Wait for Ms. Conroy to get there.

1 Continued Direct/Dr. Lembke 43

2 Thank you.

3 Q. Yes, if you could refer to your report,  
4 and I believe you do have some quotes from Pain and  
5 Policy Study Group leaders that you have identified,  
6 and if you could read those to the jury.

7 A So, first of all, just, you know, a  
8 financial list of contributions between 2000 and  
9 2007 from the Pain and Policy Study Group out of  
10 Wisconsin attested to receiving tens of thousands of  
11 dollars from certain opioid manufacturers, including  
12 Endo Pharmaceuticals, Cephalon and Alpharma, and  
13 emails --

14 MR. BARTLE: Objection. Instruct the  
15 jury --

16 THE COURT: Is that mic turned on?

17 MR. BARTLE: Sorry. Harvey Bartle,  
18 Morgan, Lewis & Bockius. We ask you to  
19 instruct the jury again with regard to  
20 connection as to pain medicine.

21 THE COURT: Neither me nor my law  
22 secretary can make out what you're saying.

23 MR. BARTLE: Sorry, your Honor. We  
24 discussed this previously. We ask you to  
25 instruct the jury again with regard to

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connection as to pain medicine.

THE COURT: I got it.

MR. SHKOLNIK: Your Honor, the witness is identifying the actual entities that made the payments.

THE COURT: I heard that.

I think the objection is really not an objection, it's a heads-up or a precautionary suggestion. And I told you this before, and I'll say it one more time, I'll probably say it a lot more as we progress. Eventually, the -- any witness' testimony has to be connected to a specific Defendant in the case because that's how you'll eventually determine whether there is or is not responsibility.

The suggestion was -- so the objection, I remind you of that and every time it happens, you'll know that. I do note that the witness' answer did name specific Defendants. So proceed.

MR. KNAPP: Your Honor, Tim Knapp on behalf of Allergan. Just an objection. There was a reference to Defendants. Of

1 Continued Direct/Dr. Lembke 45

2 course, Dr. Lembke mentioned Alpharma, which  
3 is not a defendant.

4 THE COURT: They've been told countless  
5 times "Defendants" is nondescriptive of any  
6 specific party in this lawsuit. That means,  
7 again -- I told you I'd say it again, I just  
8 did -- Defendants is just a generic term that  
9 does not identify a specific party. When the  
10 witness does identify a specific party, you  
11 may consider it, but, like I told you early  
12 on, I'll give you an instruction, certainly  
13 at the end of this case, as to your  
14 consideration of any, any expert testimony.  
15 You know, we anticipate quite a few.  
16 Proceed.

17 A I'm going to read to you a quote from a  
18 Dr. Georgeson, who was the Director of the Wisconsin  
19 Pain and Policy Study Group, in an email to a  
20 certain opioid manufacturer and he said --

21 MR. KNAPP: Your Honor, objection.

22 MR. HERSCHLEIN: Objection, your Honor.

23 THE COURT: What is the objection?

24 MR. HERSCHLEIN: The witness is reading  
25 from a document. She said she's reading a

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quote. I guess it's an out-of-court statement that the witness is going to offer for the truth. We don't even know what document --

THE COURT: Hearsay objection?

MR. HERSCHEIN: Hearsay. Apologies, your Honor.

THE COURT: Both of you say it's a hearsay objection.

MR. HERSCHEIN: Apologies, your Honor.

THE COURT: Was this document that you're reading from, was it included in your report of things that you considered in connection with your testimony, Doctor; yes or no?

THE WITNESS: Yes, your Honor.

THE COURT: Overruled.

MR. KNAPP: Your Honor, I restate the objection that --

THE COURT: So noted.

MR. KNAPP: Thank you.

THE COURT: Thank you.

A And this is a quote. "We have improved state medical board policies. Many states now have

1 Continued Direct/Dr. Lembke 47

2 improved pain opioid policies that address concerns  
3 about regulatory scrutiny. We developed much of it  
4 from behind the scenes. We wrote the two models  
5 that states have used. The medical board guidelines  
6 from California and the model guideline of the  
7 Federation of State Medical Boards.

8 Similarly, another quote written from  
9 another Director, Dr. Gillson of the Pain and Policy  
10 Study Group, this time to a representative in North  
11 Dakota. He writes quote: Well, the representative  
12 from North Dakota where they passed one of these  
13 Intractable Pain Act that made it very difficult for  
14 doctors not to prescribe opioids if the patient  
15 requested them. The representative from North  
16 Dakota writes, quote --

17 MR. HERSCHEIN: Objection, your Honor.  
18 Jurisdiction, North Dakota.

19 THE COURT: Folks, although it's a  
20 lovely state, why don't we skip that one.  
21 Go ahead.

22 MS. CONROY: I think that's the only  
23 quote, your Honor.

24 MR. SHKOLNIK: Your Honor, I don't want  
25 to say anymore than the quote that's being

1 Continued Direct/Dr. Lembke 48

2 referenced shows the national policy  
3 applicable to the Federation of State Boards.

4 THE COURT: Ms. Conroy, rephrase the  
5 question.

6 MS. CONROY: Yes.

7 Q. Can you -- can you read the quote  
8 without referring to the actual state and also let  
9 me ask you first: Does the quote you're about to  
10 read refer to more than just an individual state  
11 guideline?

12 MR. HERSCHLEIN: Same objection, your  
13 Honor.

14 THE COURT: Overruled.

15 A Yes. It refers to the Pain and Policy  
16 Study Groups' actions nationally.

17 Q. Okay. Please proceed.

18 A So the quote to the executive or the  
19 email to the executive of the Pain and Policy Study  
20 Group said: "Did you guys have a hand in this one?"  
21 And the response was from Gillson of the Pain and  
22 Policy Study Group: "I'm impressed that you could  
23 detect our fingerprints. I will wear gloves next  
24 time. Yes, we work with Bruce Levi, Executive  
25 Director of the North Dakota Medical Association to



1 Continued Direct/Dr. Lembke 49

2 change the Intractable Treatment Pain Act to a  
3 general pain statute which also removed the  
4 prescribing restrictions for addicts."

5 Q. And, Doctor, these guidelines were  
6 intended to assist clinicians in feeling more  
7 reassured about prescribing opioids to pain  
8 patients, correct?

9 A I think it even went beyond that where  
10 it actually put pressure on prescribers to prescribe  
11 opioids, and it, essentially, changed the way that  
12 opioids are used in medicine.

13 Q. Doctor, I'd now like you to refer to  
14 page 84 of the document and it is -- I think we  
15 stopped the Elmo from jumping around -- Allergan MDL  
16 01601605, and toward the top it says: At the end of  
17 the 1990s, however, the increasing frequency of  
18 diversion and abuse of opioid medications drew  
19 widespread public attention.

20 And that's true; isn't it?

21 A The end of the 1990s was really the  
22 beginning of the opioid epidemic.

23 Q. And then the last sentence of that  
24 paragraph: As a result, many clinicians became  
25 afraid to prescribe opioids for chronic benign pain;

1 Continued Direct/Dr. Lembke 50

2 do you see that?

3 A Yes, I see that, but I don't think that  
4 mischaracterizes --

5 THE COURT: The answer is just yes or  
6 no. You see that, correct?

7 Next question.

8 THE WITNESS: Yes, your Honor.

9 Q. And do you have an opinion about that?

10 A Yes, I do.

11 Q. And what is that?

12 A I think that this paragraph, although  
13 acknowledging the problem of diversion of opioid  
14 medication, gets it wrong in terms of the timing of  
15 when it drew widespread public attention or when  
16 many clinicians became afraid to prescribe opioids.

17 It really wasn't until about 2016 that  
18 the average clinician appreciated their role in the  
19 opioid epidemic, and where we started to see a shift  
20 and an awareness in the medical profession was late  
21 1990s was really when the promotion took off which  
22 changed prescribing, increased prescribing, which  
23 led to the opioid epidemic.

24 Q. And if you look at the next paragraph it  
25 says most clinicians have only a superficial

1 Continued Direct/Dr. Lembke 51  
2 understanding of what substance abuse really is, are  
3 not skilled at recognizing the symptoms of the  
4 problem and have no knowledge of the diversion and  
5 illicit resale of controlled medications. That's  
6 really what you were just talking about, correct,  
7 that it took a long time for clinicians to reach  
8 that understanding?

9 A Yes.

10 Q. And -- but in this document, at least to  
11 the sales force for Kadian, they are telling the  
12 sales force that clinicians don't have a good  
13 understanding, correct?

14 A Here in this document, yes, it states  
15 something that is true, that clinicians do not have  
16 a good understanding how to screen or intervene for  
17 addiction.

18 Q. And despite that, throughout the  
19 document we see references to low addiction rates,  
20 the benefits of opioids for chronic pain --

21 MR. KNAPP: Objection, Judge.

22 THE COURT: Sustained.

23 In fact, It's what's called repetitive  
24 direct, so go elsewhere. Thank you.

25 MS. CONROY: Great.

1 Continued Direct/Dr. Lembke 52

2 You can put that document away, Doctor.

3 I'm going to talk about Teva now, and

4 I'd like to offer into evidence P18151.

5 MR. BARTLE: I would just like to see

6 it, your Honor. I would like to see it.

7 MS. CONROY: No, we're getting it.

8 MR. BARTLE: Your Honor, we object.

9 This is not disclosed.

10 THE COURT: Let me take a look and I'll  
11 ask a question or two.

12 MR. BARTLE: This didn't become an  
13 exhibit, your Honor, until last night.

14 THE COURT: The nature of your objection  
15 is?

16 MR. BARTLE: It's not in their  
17 disclosure. She never testified about it.  
18 It's not in the report. We obtained that  
19 exhibit last evening.

20 THE COURT: Mr. Bartle suggested that is  
21 not in the expert disclosure; is it?

22 MS. CONROY: It is not, your Honor.

23 What I would like to do, this is -- I would  
24 like the doctor to assume these products and,  
25 subject to connection, offer this as an

1 Continued Direct/Dr. Lembke 53

2 exhibit.

3 THE COURT: Okay. You may pose a  
4 hypothetical question. All of you may pose  
5 hypothetical questions to any expert, but I  
6 will tell the jury the following:

7 An expert in a question and answer may  
8 be asked to assume certain facts as if they  
9 were in evidence. It's called hypothetical  
10 question. They want you to assume A, B, C,  
11 D, E and F or whatever, right.

12 The witness is permitted to answer.  
13 However, if those facts that are the basis of  
14 the hypothetical question are not  
15 independently proved during the course of the  
16 trial, that testimony will be not considered  
17 by you and I'll strike it.

18 MR. BARTLE: We maintain our objection.

19 THE COURT: So noted.

20 Q. Doctor --

21 THE COURT: No. Forget it, go ahead.  
22 It's fine.

23 Q. Doctor, I would like you to assume that  
24 Teva sold controlled substances, CT2 products that  
25 included Actiq; have you heard of Actiq?

1 Continued Direct/Dr. Lembke 54

2 A Yes.

3 Q. And could you describe what Actiq is?

4 A It's a -- essentially, it's a fentanyl  
5 lollipop.

6 Q. And what does that mean, like an actual  
7 lollipop?

8 A It means it's fentanyl on the end of a  
9 stick that you put in your mouth and the fentanyl is  
10 absorbed through the mucosa. So that's the way it  
11 gets into the bloodstream.

12 Q. And how would you describe fentanyl  
13 versus other opioid products with respect to  
14 potency?

15 A Fentanyl is one of the most potent  
16 opioid pharmaceuticals we have. It's 50 to 100  
17 times more potent than morphine.

18 Q. Doctor, I would also like you to assume  
19 that Teva sold a fentanyl patch.

20 Have you heard of a fentanyl patch?

21 A Yes.

22 Q. And how does that work?

23 A It's the same molecule fentanyl with the  
24 same potency, but instead of getting it to the  
25 bloodstream through the mucosa in your mouth, it's a

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patch that goes on the skin and it penetrates the skin and gets into the bloodstream that way.

Q. And I would like you to assume that Teva sold Fentora, are you familiar with Fentora?

A Yes.

Q. And what is that?

A That is a buccal tablet that, again, is not swallowed but rather held in the cheek and absorbed through what they call effervescence through the mucosa.

Q. And why is it that there are products for pain that are put into the mouth or can be transmitted just by putting up into your cheek?

A There are instances when patients can't take the medication in other ways. For example, they might not be able to swallow; perhaps they're at very end of life or they've had some severe type of chemotherapy and they maybe got erosive ulcers in their throat; perhaps they're intubated in the ICU, which means they got a breathing tube down their throat.

So it's important to have multiple modalities for getting the medication, in this case opioids, into the system.

1 Continued Direct/Dr. Lembke 56

2 Q. I would also like you to assume that  
3 Teva sold generic Actiq, as well as generic  
4 OxyContin.

5 Are you familiar with OxyContin?

6 A Yes.

7 Q. And who originally manufactured  
8 OxyContin?

9 A OxyContin was originally manufactured by  
10 Purdue Pharmaceuticals.

11 Q. And what is either generic OxyContin or  
12 OxyContin; what is it actually?

13 A OxyContin is a long-acting form of  
14 oxycodone and it's dosed approximately twice per  
15 day. It's a very -- it's also a very potent opioid.

16 And do you want me to get into the  
17 unique aspects of the capsule?

18 Q. No, it's okay, just what it is, and it's  
19 not fentanyl, correct?

20 A It's not fentanyl, but they are both in  
21 the class of opioid.

22 Q. Thank you.

23 MS. CONROY: I would like to offer into  
24 evidence P18376.

25 THE COURT: While they're marking that,



1 Continued Direct/Dr. Lembke 57  
2 during that question and answer, Dr. Lembke  
3 was asked to assume five or six facts, all  
4 right. Those facts must be independently  
5 established in order for that evidence to be  
6 admissible, but, like I said, we allow  
7 experts to answer hypothetical questions.  
8 Understood?

9 MR. BARTLE: Your Honor, I don't have an  
10 objection presently subject to laying a  
11 foundation. The witness has no personal  
12 knowledge of this document. To the extent it  
13 does come in later, just note our objection.

14 THE COURT: Thank you. Let me see the  
15 document.

16 You've heard the objection?

17 MS. CONROY: I'm sorry, your Honor?

18 THE COURT: I said you heard the  
19 objection?

20 MS. CONROY: Foundation?

21 THE COURT: Also, the witness has no  
22 personal knowledge of the document and  
23 foundation was a secondary objection.

24 Do I have that right, Mr. Bartle?

25 MR. BARTLE: It's both, your Honor.

1 Continued Direct/Dr. Lembke 58

2 What I'm saying is we understand it's a  
3 document she relied upon in her disclosure.  
4 She can give her opinions about this  
5 document. But she did not create it, she did  
6 not make it, she is not employed by the  
7 company. So whether or not it comes in later  
8 --

9 THE COURT: You stipulate to CPLR  
10 4540(a) document; yes or no?

11 MR. BARTLE: It was produced.

12 THE COURT: Say again.

13 MR. BARTLE: Just note my objection.  
14 I'm not trying to prohibit the witness from  
15 talking about it.

16 MS. CONROY: Yes, it was produced, your  
17 Honor.

18 MR. PRESNAL: And offered by his client.

19 THE COURT: Okay. Overruled.

20 Exception duly noted.

21 Q. Doctor, is Exhibit P18376 a type of  
22 document that you would rely on in formulating your  
23 opinions in this case?

24 A Yes, it is.

25 Q. And did you consider Exhibit P18376 in

1 Continued Direct/Dr. Lembke 59

2 formulating your opinions?

3 A Yes, I did.

4 Q. And what is the document?

5 A This is a 2005 Actiq marketing plan, so  
6 internal documents describing the company's plan for  
7 marketing their drug Actiq, the fentanyl lollipop.

8 Q. And let me show you the front page of  
9 the document, and is that the lollipop?

10 A Yes.

11 Q. Now, I would like you to turn to page 39  
12 of the document, then I will get to the Bates No. --  
13 Bates Teva MDL A 100 -- I'm sorry -- 01159362.

14 I direct your attention to where it says  
15 abuse, addiction and diversion; do you see that?

16 A Yes, I do.

17 Q. And it says: Unfortunately,  
18 undertreatment of pain continues to be a widespread  
19 problem; is that true?

20 A Pain is a huge problem in this country,  
21 but to say that it is undertreated and to then  
22 follow that with a discussion of prescription  
23 opioids is one of the ways that certain opioid  
24 manufacturers shamed doctors into prescribing  
25 opioids.

1 Continued Direct/Dr. Lembke 60

2 By juxtaposing the problem of the  
3 undertreatment of pain with marketing or promotional  
4 messages about their product, they essentially were  
5 communicating to doctors, it's undertreated because  
6 you're not willing to prescribe opioids.

7 So, yes, pain is a problem; opioids are  
8 not the answer.

9 Q. And if you could just read to the jury  
10 the next sentence, because I think that actually  
11 explains what you just said.

12 A It has been postulated that one reason  
13 why pain is undertreated is due to physician fear of  
14 prescribing opioid analgesic medications, opioid  
15 phobia.

16 Q. And what does that mean?

17 A That essentially means that the problem  
18 of undertreatment is the physicians' fault, because  
19 they're not willing to use opioids to treat pain.

20 Q. And we saw just a few minutes ago with  
21 the Kadian document, we saw the term opioid phobia;  
22 do you recall that?

23 A Yes.

24 Q. And here we see it a little different,  
25 opiophobia here in the Teva document, the Actiq

1 Continued Direct/Dr. Lembke 61

2 document, correct?

3 A Yes. There are two common spellings.  
4 One is with a D at the end of opioid. One is  
5 without the D. They're the same term, essentially.

6 Q. And being used by two different  
7 Defendants?

8 A Yes. This was a common key message that  
9 appears in multiple promotional documents.

10 THE COURT: Okay. There's an objection.

11 MR. BARTLE: I'm sorry, your Honor,  
12 Ms. Conroy states two different Defendants.

13 MS. CONROY: The Kadian Defendant that  
14 we just looked at.

15 THE COURT: I'll sustain the objection.

16 The portion of the testimony that's not  
17 specifically distributed, i.e., to Defendants,  
18 is stricken. I'm not precluding you, but be  
19 more direct in your examination.

20 Q. This morning which two Defendants did we  
21 see a reference to either opioid phobia or  
22 opiophobia?

23 A Kadian, Allergan Pharmaceuticals, and I  
24 believe we saw records as well to Endo, or not yet.

25 Q. Not yet, but here, this one.

1 Continued Direct/Dr. Lembke

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2 A This is Teva, Cephalon.

3 Q. Thank you.

4 Now, was Actiq indicated for specific  
5 kind of pain?

6 A Yes. So Actiq, the fentanyl lollipop,  
7 was FDA-approved for breakthrough cancer pain. Very  
8 specific and narrow indication, breakthrough cancer  
9 pain.

10 Q. And what does that mean if a drug is  
11 approved for a specific use by the FDA? And please  
12 use this as an example, the Actiq and cancer pain  
13 versus chronic pain.

14 A That means that if a physician were to  
15 prescribe Actiq, the fentanyl lollipop for something  
16 other than breakthrough cancer pain, they would be  
17 prescribing it off-label, off of the FDA label.

18 Q. Now, I'd like you to turn to page 45 of  
19 the document and it is Teva MDL 01159368, and I  
20 would like to direct your attention to Actiq, 2005  
21 positioning. What does that mean?

22 A That means that this is about how they  
23 were going to position their promotion of the  
24 product to prescribers.

25 Q. And if you take a look at the section in

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Continued Direct/Dr. Lembke

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bold, can you read that for the jury.

A (READING:) Actiq is fentanyl in a unique oral transmucosal delivery system that provides the most rapid onset of analgesia of any non-invasive opioid formulation available which makes it the ideal agent for BTP or rapid onset, such as BTCP.

Q. And what does BTCP stand for?

A Breakthrough pain.

Q. And what is rapid onset pain?

A Pain that comes on all of a sudden.

Q. Does breakthrough pain only occur with cancer?

A No.

Q. What about rapid onset pain?

A That is also not exclusive to cancer.

Q. So what is being said here is that Actiq is an ideal agent for breakthrough pain or rapid onset pain, both of which are not exclusively cancer pain?

A That's correct.

Q. And if you could now turn to page 37 -- actually, we'll cut it a little bit short and go to page 25.

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Continued Direct/Dr. Lembke

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And page 25 is Teva MDL 10 -- I'm sorry -- 01159348, and at the top of the page, and I'll show you on page 24, the section we're looking at is physician usage. What does that mean?

A That means how doctors were using the Actiq fentanyl lollipop.

Q. And could you read this top two sentences or just read the first sentence on the top.

A (READING:) Based on physician reporting, 90 percent of Actiq use is for breakthrough pain outside of cancer, with the majority of use 55 percent of the total being for chronic back pain. This broad use of Actiq suggests there are many prescribers who...

Q. And you can go on.

A ...understand or are experienced prescribing fentanyl, treat the pain pathophysiology, not the disease state or the etiology. Etiology means cause of the pain. Understand the benefit that Actiq affords their patients and are comfortable utilizing it beyond its labeled indication.

Q. What's happening here, Doctor?



1 Continued Direct/Dr. Lembke 65

2 A Essentially what this is saying is that  
3 the corporation recognizes that out in real life  
4 Actiq, the fentanyl lollipop, is most commonly  
5 prescribed for people who don't have any kind of  
6 cancer at all, and that in current prescribers of  
7 the Actiq fentanyl lollipop, most of their patients  
8 have things like chronic low-back pain.

9 Q. And is there a risk of addiction  
10 dependence, overdose and death with the increased  
11 use of a fentanyl lollipop like Actiq?

12 A Absolutely. So one of the core features  
13 of the opioid epidemic is not just that opioids were  
14 being prescribed for more people at higher doses for  
15 longer periods of time, but that they have been  
16 prescribed for broader indications, meaning for  
17 minor pain conditions, for chronic pain conditions,  
18 the types of conditions for which there's no  
19 evidence that the benefits of opioids outweigh the  
20 risks.

21 Q. And, Doctor, let's for a minute talk  
22 about some of the practical ways that this sort of  
23 promotion would take place of Actiq.

24 If you could turn to page 78 of the  
25 document Teva MDL A 01159401, and what I'm showing

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Continued Direct/Dr. Lembke

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you is a part of the appendix which had the budget for 2005, the tactical budget, and do you see the section that says Medical Education?

A Yes, I do.

Q. Okay. And can you describe at least what is expected to be budgeted and for what purposes.

A This shows that the makers of Actiq were willing to pay millions of dollars to promote their product to physicians and other healthcare prescribers. You could see here that they spent more than 9 million dollars to support continuing medical education.

Remember, that's the mandatory educational meetings doctors have to go to to stay up to date and to keep their license. Consultants meetings, that's the meetings with their key opinion leaders and other individuals who will help them promote their product, and also speaker training, so that's where they would create slides and essentially create a script for key opinion leaders to go out to educational conferences and use that script in order to promote their product and promote opioids more generally.

1 Continued Direct/Dr. Lembke

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2 Q. And when you were just referring to  
3 conferences, is that the increased presence at pain  
4 conferences?

5 A Yes. So a major strategy was to go to  
6 meetings and gatherings of professionals in the  
7 field of medicine.

8 So I talked a little bit about  
9 professional medical societies, like the American  
10 Academy of Pain Medicine, the American Pain Society  
11 where everybody in the field comes together once or  
12 twice a year to be at a conference, to be educated  
13 at that conference, and this shows that money was  
14 spent in order to be at those conferences, to be  
15 able to meet and greet with doctors, to tell them  
16 about their product, to give little promotional  
17 gizmos: hats, pens.

18 Q. And if we could take a look at page 80,  
19 Teva MDL A 01159403, this is appendix 8, which is  
20 the 2005 medical meeting plan, and I would direct  
21 your attention to where I've highlighted.

22 Can you explain to the jury what this  
23 is.

24 A This is just detailing a specific  
25 conference with the date and the location and how

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Continued Direct/Dr. Lembke

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many specialties in the field of pain might have shown up at that conference.

Q. So this is an American Pain Society conference that will take place in late March in 2005 in Boston, correct?

A Yes.

Q. And the products that will be discussed, GAB and Actiq, and then if you look above the specialty, what does that mean when it says specialty pain? What does that mean?

A Doctors who specialize in treating patients with pain.

Q. And so they would anticipate that 2000 doctors would be in Boston for this American Pain Society conference and their specialty would be pain, correct?

A That's right.

THE COURT: Members of the jury, I did tell you if any of you need a break just let the court officer know, okay. Don't be shy.

Q. I'm going to move on to another document. This one is in evidence, P24979, it's the Fentora Learning System, and I think you have it up there, Doctor, 24979, and it has an email on the

1 Continued Direct/Dr. Lembke 69

2 front of it, but it looks like --

3 THE COURT: Hold off. Two of our jurors  
4 would appreciate a break.

5 MS. CONROY: Okay.

6 THE COURT: We'll take a 20-minute  
7 recess. I think it takes 20 minutes just to  
8 get through the system, so to speak, so we'll  
9 take a 20-minute recess.

10 Don't discuss the case amongst  
11 yourselves or with anyone else until the  
12 appropriate time.

13 Thank you.

14 THE COURT OFFICER: All rise. Jury  
15 exiting.

16 (WHEREUPON, a short recess was taken.)

17 THE CLERK: Come to order. Supreme  
18 Court is back in session.

19 THE COURT: Be seated. Just so you  
20 know, I checked the holiday dates on the  
21 recess, we're okay. The next time the school  
22 is closed is Labor Day.

23 Okay, bring the jury back.

24 THE CLERK: I remind you, Doctor, you're  
25 still under oath.

1 Continued Direct/Dr. Lembke 70

2 THE COURT OFFICER: All rise. Jury  
3 entering.

4 THE CLERK: All jurors are present and  
5 properly seated.

6 THE COURT: Be seated. Thank you.

7 Ms. Conroy.

8 CONTINUED DIRECT EXAMINATION OF DR. LEMBKE BY

9 MS. CONROY:

10 Q. Doctor, just before the break we were  
11 looking at P24979, it's the Fentora Learning System;  
12 do you have that?

13 A Yes.

14 Q. And could you remind the jury what is  
15 Fentora?

16 A Fentora is the fentanyl tablet that goes  
17 into the cheek that is absorbed transmucosally.

18 Q. And who manufactures and sells Fentora?

19 A Teva, Cephalon.

20 Q. And I'd like to direct -- and what is  
21 Fentora indicated for?

22 A Breakthrough cancer pain.

23 Q. If you could take a look at page 40 of  
24 the document and it is Teva MDL A 00890346, section  
25 that says: Like patients, caregivers may need

1 Continued Direct/Dr. Lembke 71

2 reassurance that few people using opioids for a  
3 legitimate medical reason become addicted to the  
4 drug. Do you see that?

5 A Yes, I do.

6 Q. "Few people," that's not common or very  
7 common, correct?

8 A To say "few people" is inconsistent with  
9 the science showing that addiction is common or very  
10 common in people being prescribed opioids for  
11 chronic pain.

12 Q. Is that statement false?

13 A Yes.

14 Q. And the statement goes on and says: And  
15 that physical dependence to a drug is easily  
16 overcome to scheduled dose decreases if the patient  
17 improves to the point where opioids are no longer  
18 needed; do you see that?

19 A Yes, I do.

20 Q. Is physical dependence to a drug easily  
21 overcome?

22 A Not for most people, no.

23 Q. And why is that?

24 A Because the brain and the body adapts to  
25 the presence of the drug, so literally it changes

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the brain. So when a dose goes down or the medication is stopped abruptly, patients will experience the classic syndromes of opioid withdrawal. And even beyond the immediate two to three weeks of acute physical withdrawal, there can be a persistent psychological syndrome called protracted abstinence syndrome characterized by ongoing irritability, depression, anxiety, insomnia and craving for the drug.

Q. Is there a difference between physical dependence to fentanyl versus oxycodone or a different type of opioid?

A Well, because fentanyl is so much more potent than other opioids, you're effectively giving that person more opioids. We do know that the risk of addiction is dose and duration dependant, and addiction is commonly accompanied by physical dependence.

And when I say that it's dose and duration dependant, what I mean is that the more opioid you're on, and the longer you're on them, the more likely you are to become addicted to that opioid.

Q. Is it false that physical dependence to



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Continued Direct/Dr. Lembke

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a drug is easily overcome through scheduled dosing decreases?

A That's false for the vast majority of people, yes.

Q. If you could turn to page 45 of the document, which is Teva MDL A 00890351.

And I think we took a look at this document the other day. In patients without personal or family history of substance abuse addiction resulting from exposure to opioid therapy is uncommon. Is that statement true?

A No.

Q. Because the risk of addiction is common to very common, correct?

A Yes. And because -- although it is true that if you have a personal or a family history of addiction and your doctor gives you an opioid for pain, you're more likely than the average person to get addicted to that opioid because of the genetic or inherited factors that we talked about, as well as the childhood nurture factors.

But even though that is true, the biggest risk of getting addicted to an opioid that a doctor gives you for pain is how much they gave you

1 Continued Direct/Dr. Lembke 74

2 and how long you were on it, and that risk trumps  
3 the other inborn genetic risks based on personal or  
4 family history.

5 Furthermore, even with no personal or  
6 family history of getting addicted to anything, it's  
7 still common for patients to get addicted when they  
8 get put on an opioid by their doctor, and doctors  
9 can't predict who will and will not get addicted  
10 once they get started on opioids.

11 Q. Is this statement that addiction risk is  
12 uncommon false?

13 A Yes. So this is, again, a reference to  
14 that Porter and Jick letter to the editor, which was  
15 cited as a study and isn't really a study.  
16 Remember that hospitalized study, study of  
17 hospitalized patients showing that there are more  
18 than four out of 11,882 developed a "narcotic  
19 addiction" and how that is not really evidence  
20 because it was a hospitalized sample, which is not  
21 consistent with the real world population of  
22 outpatients walking around with things like chronic  
23 low-back pain, and because many of those individuals  
24 just got a single dose or got a very low dose for  
25 short duration.

1 Continued Direct/Dr. Lembke 75

2 So, again, this is misleading because it  
3 looks like it blends science in numbers by using a  
4 citation that wasn't robust enough to be used for  
5 this kind of statement.

6 Q. And now if you could turn to page 49,  
7 Teva MDL A 00890355. You're going to be looking at  
8 the top of the page. It says: Pain appears to  
9 reduce the euphoric effects of opioids so people  
10 taking opioids to manage their pain may be at a  
11 lower risk for addiction.

12 What are they saying here?

13 A So this is a really important misleading  
14 key message that was put out there by certain opioid  
15 manufacturers and it had a huge impact on doctors.

16 Q. Doctor, can I just stop you there.

17 We can talk specifically, this is a  
18 message being put out by Teva with respect to  
19 Fentora, correct?

20 MR. BARTLE: Objection, your Honor. I'm  
21 sorry, your Honor, never mind. Withdraw the  
22 objection.

23 Q. I'm sorry, you can go ahead, Doctor.

24 THE COURT: Go ahead.

25 A Okay. So just to answer the question,

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what this statement essentially stands for is that there's something biologically unique about a patient who has pain, such that if they take an opioid that their doctor gave them for the pain, they're somehow magically immune from getting addicted.

This was very persuasive for doctors trained starting in the late 1990s for the last two decades.

In doing research for my books I talked to many doctors about what their education and impressions were of opioids for pain and many of them told me that they were convinced by statements like this that somehow as long as they were prescribing the opioid to a real patient with real pain, that the patient was very unlikely to get addicted. That's how we ended up with the opioid epidemic. This is patently not true.

Q. Is this statement false?

A Yes, it is.

Q. Let's take a look at the next paragraph where it says: Certain behaviors are sometimes mistaken for addiction. If patients receive inadequate pain relief they may exhibit drug seeking

1 Continued Direct/Dr. Lembke 77

2 behaviors. This is called pseudoaddiction.

3 What is pseudoaddiction?

4 A Pseudoaddiction is a made-up term and it  
5 essentially means fake addiction.

6 Q. And where does this originate from?

7 A This term was originally coined by two  
8 authors who published a case report in a peer-review  
9 medical journal. A case report is a description of  
10 a single patient.

11 And what they described was a young man,  
12 who I believe had leukemia, who had pain and it was  
13 being treated with opioid, but who engaged in what's  
14 called drug seeking behaviors, like making up, you  
15 know, gestures to demonstrate that he was in more  
16 pain, putting a lot of work into getting more pain  
17 medicine, which these authors then describe as  
18 pseudoaddiction, essentially, essentially saying  
19 that if you have a patient who is demonstrating all  
20 the signs and symptoms of having become addicted,  
21 they're not really addicted, they're pseudo addicted  
22 and in pain, and you need to go up on the pain  
23 medicine.

24 And the only real criteria for sorting  
25 out, according to these -- this concept, who's

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addicted and who's pseudo addicted is to ask the patient if they have pain, and if they say yes, then you should go up on the pain medicine, because you should treat to whatever the patient says, ignoring anything else. That is essentially what happened.

And the problem with this concept was that it made it very difficult for prescribers to diagnose addiction in the context of treating a patient with opioid for pain, because even when you saw somebody who was doing all the things that people with addiction do: lying, you know, getting drugs from multiple prescribers, you know, doing a lot of thinking, a lot of effort to get more opioids, you really weren't allowed to say that they were addicted because you had to call them pseudo addicted to increase the opioid.

The other tragic impact of this concept is it really deprived those individuals who became addicted through their doctors' prescriptions getting appropriate addiction treatment that might have saved their lives.

Q. Doctor, is using the concept of pseudoaddiction false promotion?

A Yes. It's false, but it also encouraged

1 Continued Direct/Dr. Lembke 79

2 higher dosage of opioid prescribing, right, because  
3 the solution for pseudoaddiction was to go up on a  
4 meter.

5 MR. BARTLE: I'm going to object to this  
6 question and answer and request a short  
7 sidebar on this. It's outside the scope.

8 THE COURT: Give me the question back,  
9 please. Oh, by the way, you're all directed  
10 to the Court's decision short form order  
11 dated November 12th 2020 as concerns --

12 MR. BARTLE: I believe that's what I'm  
13 referring to, your Honor.

14 THE COURT: So you're suggesting he's  
15 outside the scope of an allowable area?

16 MR. BARTLE: Correct.

17 THE COURT: Okay. Read me the question,  
18 please.

19 (WHEREUPON, the requested portion was  
20 read by the reporter.)

21 THE COURT: Marketing is out of bounds;  
22 promotion is not.

23 Overruled.

24 Q. I believe you actually answered the  
25 question already; did you?

1 Continued Direct/Dr. Lembke 80

2 A Yes.

3 THE COURT: The Court notes in the  
4 footnote there's a distinction between the  
5 two that's subject to consideration.

6 Go ahead.

7 MS. CONROY: Thank you, your Honor.

8 Q. Doctor, is there any empirical evidence  
9 to support the concept of pseudoaddiction?

10 A No. In reviewing the literature there  
11 is no empirical evidence to support the concept of  
12 pseudoaddiction. No scientific evidence to support  
13 this concept.

14 Q. You can put that document away, doctor,  
15 or both of those documents.

16 And for my next question, doctor, I  
17 would like you to assume that there is an Endo  
18 document entitled: Opioid Analgesic Advanced Sales  
19 Training from 2003, okay?

20 MR. HERSCHLEIN: Objection, your Honor.  
21 That's improper.

22 THE COURT: Let's see where it goes.

23 Oh, by the way, this document you're  
24 asking the witness to assume, has it been  
25 exchanged?



1 Continued Direct/Dr. Lembke 81

2 MS. CONROY: Yes, your Honor.

3 THE COURT: Exchanged in the course of  
4 discovery?

5 MS. CONROY: Yes, it was. And it was  
6 used by both Defendants and Plaintiffs in  
7 opening statements.

8 THE COURT: Okay.

9 MR. HERSCHLEIN: Your Honor, it's not in  
10 her report. It's not part of her referenced  
11 materials.

12 Your Honor ruled clearly last week that  
13 it's out of bounds. Those are your words.

14 THE COURT: This is a very late  
15 disclosure?

16 MR. HERSCHLEIN: Last night, 7:12.

17 THE COURT: Okay. Sustained.

18 MS. CONROY: Thank you, your Honor.

19 THE COURT: I don't know if you have to  
20 thank me for sustaining your objections, but  
21 I'll take it.

22 MS. CONROY: That's okay. We'll get to  
23 that document.

24 Q. I would like to draw your attention to a  
25 document that is in evidence, P23771, and it's the

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Oxymorphone learning system.

MR. HERSCHEIN: Your Honor, at the appropriate time we would ask for the limiting instruction that you gave on this document last week, because we're coming back to it.

THE COURT: Okay. You have to give me a clue which limiting instruction I gave.

MR. HERSCHEIN: It has to do with the AOD.

THE COURT: Oh, okay.

There was, members of the jury, there was a prior dispute between Endo and the State of New York which was resolved back in 2016. It was resolved by something called an AOD, an assurance of discontinuance. That thing that we call an AOD eliminated certain product and certain conduct from consideration, certainly going back in time.

As we progress I will, in all probability, be giving you additional instructions regarding that. The medication is Opana, it was the subject of the dispute, and that dispute was resolved. Resolved,

1 Continued Direct/Dr. Lembke 83

2 resolved with no admission of liability or  
3 fault, all right, so keep that in mind.

4 Was that the one I gave or close enough?

5 MR. HERSCHLEIN: Pretty close, your  
6 Honor. Also Opana ER.

7 THE COURT: Okay, Opana ER, yes.

8 MR. SHKOLNIK: Your Honor, the  
9 instruction is supposed to be limited to the  
10 State and not the Counties.

11 THE COURT: By the way, the Counties,  
12 yeah. The Counties were not a party -- thank  
13 you for reminding me -- the Counties were not  
14 a party to that dispute, so whatever you may  
15 hear during Miss Conroy's examination, to the  
16 extent that it refers to this Opana ER and  
17 has some connection to that thing I called an  
18 AOD, it's not applicable to the State.

19 Go ahead.

20 Q. Doctor, if you would turn to page 25 of  
21 the Oxymorphone Risk Management Program.

22 And do you see where it says, Approach  
23 to selling OxyContin?

24 A I do.

25 Q. And who was the manufacturer of

1 Continued Direct/Dr. Lembke

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2 OxyContin?

3 A Purdue Pharmaceuticals.

4 Q. And which Defendant is writing this  
5 document?

6 A This document is being written by Endo  
7 Pharmaceuticals.

8 Q. And it says: With the initial success  
9 of OxyContin, Purdue put a lot of effort into  
10 marketing and promoting it. They promoted the use  
11 of OxyContin for both cancer and non-cancer pain,  
12 significantly increased their sales force and used  
13 multiple promotional approaches.

14 Do you see that?

15 A Yes, I do.

16 Q. And you're familiar with that from your  
17 research, correct?

18 A Correct.

19 Q. If we could turn the page.

20 Endo references possible factors  
21 contributing to problems. Do you see that?

22 A Yes, I do.

23 Q. And it says: Once the abuse and  
24 diversion problem with OxyContin became known, the  
25 reasons for contributing to the problem began to be

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investigated; do you see that?

A Yes, I do.

Q. And then down a little bit further it talks about improper marketing; do you see that?

A Yes.

Q. You had read through this document?

A Yes, I have.

Q. Was Endo aware of the consequences of the misleading and false promotion by Purdue of its drug OxyContin?

MR. HERSCHEIN: Objection, your Honor.

I think there's a mill on corporate knowledge.

THE COURT: The way the question was put to you I'll sustain the objection.

You're asking what somebody was aware of, so even though it's an inanimate object, a corporation, you can't call for the operation of the mind of the entity.

Go ahead. I'm not precluding you, but I'm suggesting another way perhaps.

MS. CONROY: I'll rephrase, your Honor.

Q. Were you able to determine from the pages 26 and 27, information that Endo was able to

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determine from the problems that Purdue faced with  
OxyContin?

THE COURT: Just say yes or no.

A Yes.

Q. And what were they?

A Well, it's clear from this document that  
Endo Pharmaceuticals was well aware that Purdue was  
cited by the FDA for things like advertisements in  
journals, for suggesting that OxyContin could be  
used as initial therapy or was often referred to as  
first line treatment. That it could be used in  
older people. And importantly, that Purdue  
overstated the benefits and minimized the addiction  
risk of its products.

MR. HERSCHLEIN: Your Honor, I would  
object and move to strike the answer which  
began "it was clear that Endo was well  
aware." It's directly contrary to the  
ruling.

THE COURT: I'll strike -- that portion  
of the answer is stricken. If you can go to  
a specific -- in other words, when I strike  
it, remove it from your mind, that portion of  
the answer. You can go to the document.

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2 MS. CONROY: I will, your Honor.

3 THE COURT: Thank you.

4 Q. Doctor, do you see where it says, under  
5 Improper Marketing, there are explanations of what  
6 Purdue was cited for by the FDA; do you see that?

7 A Yes, I do see that.

8 Q. And one was for several advertisement  
9 violations between 2000 and 2003; do you see that?

10 A Yes.

11 Q. And this is an Endo document reciting  
12 this, correct?

13 A That is correct.

14 Q. And then they also talk about an  
15 advertisement in a medical journal that implies that  
16 OxyContin had been studied in all types of  
17 arthritis; do you see that?

18 A That's correct.

19 Q. Is arthritis a chronic pain -- something  
20 that creates chronic pain?

21 A Yes.

22 Q. It also talks about OxyContin could be  
23 used as initial therapy in elderly patients without  
24 support for any of those plans; do you see that?

25 A Yes, I do.

1 Continued Direct/Dr. Lembke 88

2 Q. And that is Endo reciting what it  
3 understood Purdue to have done that was improper?

4 A Yes.

5 Q. Then it says: A second more serious  
6 citation was for journal ads.

7 What are journal ads?

8 A They're advertisements in medical  
9 journals that doctors read.

10 Q. (READING:) And those ads minimized the  
11 drug's risks and overstated its efficacy; do you see  
12 that?

13 A Yes, I do.

14 Q. (READING:) Failed to present  
15 information from the boxed warning on potentially  
16 fatal risks and abuse potential and omitted  
17 information about limitations on its indication; do  
18 you see that?

19 A Yes, I do.

20 Q. When it talks about limitations on its  
21 indication, what does that refer to?

22 A That means they went beyond what the FDA  
23 said the drug could be used for.

24 Q. And is that similar to what we were  
25 talking about when we were talking about Fentora and



1 Continued Direct/Dr. Lembke 89

2 Actiq being indicated only for cancer, for  
3 breakthrough cancer pain?

4 A Yes, that's a similar example.

5 Q. Then it says: Purdue's website for  
6 OxyContin also had information inconsistent with its  
7 labeling and lacked risk of information for use in  
8 postoperative pain; do you see that?

9 A Yes, I do.

10 Q. And is it your opinion that this  
11 information written by Endo in its Oxymorphone  
12 document was known by Endo?

13 A Yes. If they wrote it in their  
14 document, they clearly knew it.

15 Q. Then it talks about several videos  
16 produced by Purdue were found to contain other  
17 substantiated claims about patient's quality of  
18 life, inability to perform activities of daily  
19 living while minimizing risks and claiming a low  
20 likelihood of addiction; do you see that?

21 A Yes, I do.

22 Q. It's your opinion Endo was aware of this  
23 and aware that Purdue had been found to have  
24 improperly marketed OxyContin by the FDA as a result  
25 of some of these claims?

1 Continued Direct/Dr. Lembke 90

2 MR. HERSCHEIN: Objection, your Honor.

3 THE COURT: Can I hear that question  
4 again. Can you read that back, please.

5 (WHEREUPON, the requested portion was  
6 read by the reporter.)

7 THE COURT: Overruled.  
8 You can answer.

9 A Yes, it's clear to me that Endo  
10 Pharmaceuticals was aware of what Purdue, what they  
11 wrote about it in their own document.

12 Q. If you could turn to page 14 of the  
13 document, the actual page 14. Could you read where  
14 I have highlighted. Can you see it?

15 A Yes, I can see it. Do you want me to  
16 read it out loud?

17 Q. Oh, read it out loud, I'm sorry.

18 A (READING:) Physicians can differentiate  
19 addiction from pseudoaddiction by speaking to the  
20 patient about his/her pain and increasing the  
21 patient's opioid dose to increase pain relief.

22 Pseudo-addictive behaviors, such as  
23 clock watching, counting down the time until the  
24 next dose will resolve when the pain is properly  
25 treated.

1 Continued Direct/Dr. Lembke 91

2 Q. Are those statements false?

3 A Those are false and misleading, yes.

4 Q. Doctor, in your opinion, did Endo jump  
5 on the Purdue bandwagon with respect to the  
6 promotion of its drug Oxymorphone?

7 MR. HERSCHLEIN: Object to the form,  
8 your Honor.

9 THE COURT: Sustained. Sustained.

10 Q. Is the pseudoaddiction claim false  
11 promotion, in your opinion?

12 A Yes, it is.

13 Q. Thank you. You can put that one away.

14 Doctor, have all of the prescription  
15 opioids that we've talked about today been approved  
16 by the Food and Drug Administration, the FDA?

17 A Yes, they have.

18 Q. And have you assigned some  
19 responsibility for the opioid epidemic to the FDA?

20 A Yes, I have.

21 Q. Are you an expert in FDA regulations?

22 A No, I'm not.

23 Q. Do you understand that Dr. Kessler,  
24 former Commissioner of the FDA, is going to testify  
25 here?

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A Yes. That is my understanding.

Q. Are you familiar with the labels that come with prescription opioids?

A Yes.

Q. And do those labels include a risk of addiction and overdose?

A Yes, they do.

Q. Now, do doctors get more of their information about prescription opioids from labels or from somewhere else, in your opinion?

A From somewhere else. Labels are not the main source of information for doctors. It's all the other things we talked about: continuing medical education, key opinion leaders, journal articles, the Joint Commission of Quality Measures Guidelines, the Federation of State Medical Boards tells them what they need to do, what their teachers tell them they need to do.

Q. Does the FDA sell opioids?

A No, it does not.

Q. Do they profit -- does the FDA profit from opioid sales?

A Not as far as I know, no.

Q. Does the FDA make any promotional

1 Continued Direct/Dr. Lembke 93

2 statements about opioids?

3 A No.

4 Q. Do you draw any distinction between the  
5 responsibility of the manufacturing Defendants,  
6 Endo, Allergan and Teva on the one hand from the FDA  
7 on the other?

8 MR. BARTLE: Your Honor, I still make my  
9 objection based upon your prior ruling  
10 regarding scope of this witness' testimony.

11 THE COURT: Can I have the question  
12 back.

13 (WHEREUPON, the requested portion was  
14 read by the reporter.)

15 THE COURT: Overruled.

16 Just yes or no.

17 A Yes, I do draw a distinction.

18 Q. And what is that distinction?

19 A To me, the responsibility and obligation  
20 of certain opioid manufacturers promoting these  
21 products is much greater in regards to the opioid  
22 epidemic. Essentially, they were maximizing profits  
23 at the expense of public health and safety.

24 THE COURT: Ms. Conroy, the nature of  
25 your objection was, I think, was that you

1 Continued Direct/Dr. Lembke 94

2 mentioned three parties in connection with  
3 one question, and I think it was suggested --

4 MR. BARTLE: That was not the nature of  
5 my objection.

6 THE COURT: It would have been a good  
7 one.

8 MR. BARTLE: It wasn't the one I made.

9 THE COURT: It would have been a good  
10 one. I think Saturday Night Live would say,  
11 Never mind...

12 Go ahead.

13 Q. Dr. Lembke, I want you to assume that  
14 each of the three Defendant manufacturers, Endo,  
15 Teva and Allergan in their opening statements --

16 MR. BARTLE: Your Honor, I would object  
17 to this question with regard to corporate  
18 separateness.

19 MS. CONROY: All right, I'll do it that  
20 way, that's fine.

21 THE COURT: Sustained.

22 Q. I want you to assume that Endo in its  
23 opening statement by Mr. Herschlein argued that the  
24 New York State Department of Health itself repeated  
25 the message that addiction is rare in patients

1 Continued Direct/Dr. Lembke 95

2 taking opioids for pain.

3 Does it surprise you that the New York  
4 State Department of Health would make a statement  
5 like that: Addiction is rare?

6 MR. HERSCHEIN: Objection, your Honor.  
7 I believe your Honor ruled last week this  
8 witness is not to be commenting on attorney  
9 statements.

10 THE COURT: No, no, I don't think I did.  
11 I certainly don't think I did. I customarily  
12 will allow a witness to be confronted with a  
13 suggestion that was made. However, I don't  
14 like the word "surprise."

15 MS. CONROY: Okay.

16 THE COURT: So sustained.

17 MR. HERSCHEIN: Second objection, your  
18 Honor, is this is not in her report.

19 THE COURT: This is not what?

20 MR. HERSCHEIN: This is not within the  
21 witness' expert report.

22 THE COURT: Okay. Overruled. You can  
23 answer.

24 Q. Let me rephrase --

25 THE COURT: Take the word surprise out.

1 Continued Direct/Dr. Lembke 96

2 Use a different word. There's got to be a  
3 better one.

4 Q. Was that unexpected?

5 A Yes.

6 Q. And why is that?

7 A The fact that these misleading messages  
8 appear in other places is evidence of the  
9 effectiveness of the promotional campaign.

10 Certainly opioid manufacturers were able  
11 to infiltrate every layer of medicine and medicine  
12 regulatory bodies and policymakers in order to  
13 promote opioids as a class, which in turn increased  
14 sales of their opioid products.

15 Q. And would your answer be the same if a  
16 statement was made by Teva or by Allergan?

17 A Yes, it would.

18 Q. Thank you.

19 Now, we have looked at several  
20 promotional statements that were made by certain  
21 opioid Defendants, correct, over the last three  
22 days?

23 A Yes, that's correct.

24 Q. And were those messages, some of them,  
25 and I'll go into them specifically, misleading?



1 Continued Direct/Dr. Lembke

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2 A Yes.

3 Q. And one of them is addiction is rare; is  
4 that right?

5 A Well, the word "rare" itself is not, is  
6 not necessarily always used. Sometimes the word is  
7 uncommon or there's minimal risk as long as you're  
8 prescribing to a patient with pain.

9 Q. Did you see promotional statements  
10 talking about addiction is rare or uncommon or  
11 minimal risk or something along those lines when you  
12 looked at Allergan Finance, LLC documents?

13 A Yes.

14 Q. Did you see such misleading or false  
15 messages about addiction in Endo documents?

16 A I have seen such statements in Endo  
17 documents, yes.

18 Q. And what about in Teva documents?

19 A Yes.

20 Q. Pseudoaddiction, did you see misleading  
21 messages about pseudoaddiction in Allergan Finance  
22 documents?

23 A Yes.

24 Q. In Endo documents?

25 A Yes.

1 Continued Direct/Dr. Lembke

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2 Q. In Teva documents?

3 A Yes.

4 Q. And did you see statements about  
5 dependence and that it's easy to deal with or  
6 normal, things along that line?

7 A Yes.

8 Q. Did you see such statements in Allergan  
9 Finance documents?

10 A Yes.

11 Q. In Endo documents?

12 A Yes.

13 Q. In Teva documents?

14 A Yes.

15 Q. Were all of those statements made --  
16 strike that.

17 Those statements, were they false?

18 A False and misleading, yes.

19 MR. BARTLE: Your Honor, I would ask  
20 that that document be marked and we be  
21 provided copies of it.

22 THE COURT: That's fair.

23 MS. CONROY: That's fine.

24 THE COURT: Let's mark it now.

25 (WHEREUPON, Document was hereby marked

1 Continued Direct/Dr. Lembke 99

2 as Plaintiffs' Demo 500 in evidence.)

3 THE COURT: We'll see that copies are  
4 distributed at the next break.

5 MS. CONROY: We can make a copy now.

6 Q. Doctor, in your opinion, is there a  
7 relationship between false promotional messages and  
8 the increased sale of opioids?

9 A Yes.

10 Q. And what is that relationship?

11 MR. HERSCHEIN: Objection, your Honor.  
12 This is footnote 8.

13 THE COURT: The document is right in  
14 front of me as we speak. It's the  
15 question -- I'll sustain the objection. I'm  
16 not precluding you, but if you don't have it,  
17 just look at footnote number 8 in the  
18 November 12th 2020 short form order.

19 MS. CONROY: Your Honor, I'm referring  
20 to promotional messages in this question.

21 THE COURT: Make it promotional.

22 Q. Is there a relationship between  
23 promotional messages and the sale of opioids?

24 MR. HERSCHEIN: Your Honor --

25 THE COURT: I think the sales aspect of

1 Continued Direct/Dr. Lembke 100

2 the question is the basis of the objection,  
3 so I'll sustain it, but there's something  
4 other than sales between --

5 MS. CONROY: Sure.

6 Q. Is there a relationship between  
7 promotional messages and physicians prescribing  
8 opioids?

9 A Yes.

10 MR. HERSCHEIN: Your Honor, the  
11 objection is there's not been a foundation  
12 laid as required by footnote 8 for the  
13 distinction between marketing and promotion.  
14 The Defendants' position is that there is no  
15 distinction.

16 MR. PRESNAL: With all due respect -

17 THE COURT: Do me a favor, put your mask  
18 down when you talk to me.

19 MR. PRESNAL: Sorry, Judge. With all  
20 due respect, she has examined this confluence  
21 between this massive marketing campaign and  
22 the fact that there was a massive increase in  
23 the prescribing of opioids as described it  
24 this paradigm shift in the treatment of  
25 chronic pain.

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2 MR. KNAPP: Your Honor, again, I would  
3 object to the colloquy as inappropriate.

4 THE COURT: Ms. Conroy, you may seek  
5 testimony between what we've seen and  
6 quantity, all right.

7 Q. Doctor, have you seen a relationship  
8 between the promotional messages that you reviewed  
9 and the quantity of opioids in New York State, Long  
10 Island, or the Counties?

11 THE COURT: Just yes or no.

12 A Yes.

13 Q. And what is that relationship?

14 A The promotional messages targeting  
15 doctors and other healthcare institutions led to  
16 increased prescribing of opioids, which led to a  
17 greater supply of opioids in the community.

18 Q. And what did that lead to?

19 A That led to more people becoming  
20 addicted to opioids, more people overdosing on  
21 opioids and more people dying from opioids.

22 Q. And where did that take us?

23 A Those individuals, many of them,  
24 progressed to heroin and illicit fentanyl.

25 Q. And is there a term for that, that

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2 progression to heroin or illicit fentanyl?

3 A Yes. It's called the gateway phenomenon  
4 or gateway hypothesis where individuals start out  
5 with pain pills prescribed by their doctor or  
6 perhaps pain pills that were prescribed to somebody  
7 else in the family, which they took from the  
8 medicine cabinet for the right reasons, and then the  
9 individual ultimately gets addicted to the opioid  
10 and then looks for cheaper and more available  
11 sources over time, which is illicit sources like  
12 heroin and illicit fentanyl.

13 Q. Doctor, you call that what?

14 A The gateway theory or the gateway  
15 phenomenon.

16 Q. Is that your term or do others use that  
17 as well?

18 A That's a term that I have used, as well  
19 as -- and others have used that term as well.

20 MS. CONROY: Thank you, Doctor. I have  
21 no further questions at this time.

22 THE COURT: Mr. Shkolnik?

23 MR. SHKOLNIK: Your Honor, I'm going to  
24 have about 45 minutes to an hour. Could we  
25 take our -- I could condense it if we took

1 In Re: Opioid Trial 103

2 our lunch break at 12:15 or 12:30, that would  
3 really help, unless the Court wants me to  
4 stop. I will be happy to do it either way.

5 THE COURT: That's okay. Members of the  
6 jury, are you hungry?

7 We'll break for lunch. We'll resume at  
8 1:30. Don't discuss the case among  
9 yourselves or with anyone else until the  
10 appropriate time.

11 Thank you.

12 MS. CONROY: Thank you.

13 THE COURT OFFICER: All rise. Jury  
14 exiting.

15 THE COURT: See everybody at 1:30.  
16 Thank you.

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In Re: Opioid Trial

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C E R T I F I C A T I O N

I, Stephanie Casagrande Hague, CSR, RPR,  
an Official Court Reporter of the State of  
New York, County of Suffolk, do hereby  
certify that the above is a true and accurate  
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in the above-entitled action on this day;

Furthermore, photocopies made of this  
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STEPHANIE CASAGRANDE HAGUE, CSR, RPR  
Official Court Reporter



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